DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3539n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

MAR 1 3 2000

Certified Mail
Return Receipt Requested

Bruce Warden, M.D., Radiologist
Tri-City Outpatient Imaging
3998 Vista Way, Suite E
Oceanside, CA 92056

W/L 43-00
Inspection ID: 1275970007

Dear Dr. Warden:

We are writing to you because on 2/15/2000, your facility was inspected by a representative of the state of California, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

1. **Phantom QC records were missing for 5 weeks for unit 1, Siemens Medical Systems, OTH, room Room 1**

2. **Phantom QC records were missing for 6 weeks for unit 3, General Electric Co. (GE Medical Systems), OTH, room Room 3**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the level-2 findings that were listed on the inspection report provided to you at the close of the inspection. These level-2 findings are:

1. **Corrective action for processor QC failures were not documented at least once for processor 0000000001, Kodak, Other, room Daylight at site Tri-City Outpatient Imaging**

2. **Mammograms were processed in processor 0000000001, Kodak, Other, room Daylight at site Tri-City Outpatient Imaging, when it was out of limits on 2 days**

3. **Processor QC records were missing 2 consecutive days for processor 0000000001, Kodak, Other, room Daylight at site Tri-City Outpatient Imaging**

4. **Processor QC records were missing 5 out of 22 days of operation in month 04/1999. Processor QC records missing 23%, for processor 0000000001, Kodak, Other, room Daylight at site Tri-City Outpatient Imaging**

5. **Phantom QC records were missing for at least two weeks but less than four weeks for unit 2, Siemens Medical Systems, OTH, room Room. 2**

6. **The radiologic technologist did not meet the continuing education requirement of having completed a min. of 15 CEUs in mammography in a 36 month period: LINDA WERNET (6 CEU's in 36 months)**

It is necessary for you to act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter.

- The specific steps you have taken to correct all of the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.

- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. **(Note: Patient names or identification should be deleted from any copies submitted).***

*this note is not applicable for letters which also address patient notification.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html <http://www.fda.gov/cdrh/dmqrp.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,

Thomas L. Sawyer

Acting District Director